

## REMARKS

### Introductory Comments

Reconsideration of the above-identified application in view of the above amendments and foregoing arguments is respectfully requested.

Claims 31 and 34 are pending and under consideration. Claims 32-33 have been deleted. Claim 31 has been amended as explained below. Claim 34 has been amended to change its dependency. No new matter has been added as a result of these amendments. Additionally, claims 35-38 have been added. No new matter has been added as the result of the addition of these claims.

### Rejection of Claims 31-34 Under 35 U.S.C. § 112, First Paragraph

Claims 31-34 are rejected under 35 U.S.C. § 112, first paragraph, for not enabling a person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope of the claims. Applicant respectfully traverses this rejection with respect to pending claims 31 and 34.

Specifically, the Examiner contends that the specification, while being enabling for a method of crossing the proprietary *Impatiens flaccida* plant disclosed on page 4 with a *I. Hawkeri* Java series and selecting an interspecific plant with a trailing habit, does not reasonably provide enablement for all lines of *I. flaccida*. The Examiner states that as noted by Applicant on page 3 of the specification, Arisumi (1980) and Arisumi (1985) state that no seeding were obtained from crossing *I. flaccida alba* with *I. herzogii*. The Examiner therefore concludes that based on this finding, one cannot assume that Applicant's own experiment would always work without Applicant's proprietary impatiens line deposited at the American Type Culture Collection.

Applicant respectfully submits that it is improper for the Examiner to make this conclusion. Applicant specifically refers to the declaration of Dr. Trees

provided by Applicant in paper no. 29, provides the observation of over 100 successful crossings between *Impatiens flaccida* and *I. Hawkeri*.

The Examiner also reiterates the rejection of the claims for requiring undue experimentation with respect to the *Wands* factors as applied in the previous Office Action. The Examiner states that if the Applicant feels the breadth of the claims, the nature of the invention, the level of ordinary skill, and the amount of direction provided by the Inventor are important, then the Applicant should explain why they are essential.

In *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988), the Court discussed the issue of undue experimentation. The Court states that in order for the specification to be enabling, it must teach those skilled in the art how to make and use the full scope of the invention without undue experimentation. However, the Court also states that there can be some experimentation required and the specification is still enabling. *Id.* The Court provides the following factors only in determining whether a specification is enabling in unclear cases: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence or absence of working examples, 4) the nature of the invention, 5) the state of the prior art, 6) the predictability or unpredictability of the art, and 7) the breadth of the claims. *Id.*

Applicant respectfully submits that for reasons set forth below, the subject matter as claimed does not fall within the type of cases that requires one to question whether undue experimentation is required in order to make and/or use the claimed invention. However, since the Examiner questions this issue with respect to Applicant's invention, the Examiner has the burden to set forth the reasons for her rejection. The Examiner has not performed this analysis because the Examiner has not discussed all of the factors set forth in *In re Wands*. Applicant submits that since the Examiner bases her conclusion from only one example crossing from the Arisumi publication, the Examiner should therefore discuss all of the *Wands* factors.

Nevertheless, Applicant hereby discusses why the Examiner's rejection for non-enablement because of undue experimentation should be withdrawn based on the *Wands* factors.

With respect to the first factor, Applicant submits that the quantity of experimentation is not necessarily high for the claimed invention. This is because of the high number of success in crossings that involve *Impatiens flaccida*, as discussed in Applicants Response dated November 23, 2003, pages 3-4. Second, the amount of direction or guidance provided by Applicant in the specification is adequate. Applicant not only provides working examples of the invention such as the two hybrids having a trailing habit produced from the inventive method, but Applicant also discusses other known hybrids in the specification.

Third, there is a presence of working examples provided in the specification instead of an absence of working examples. As noted above, Applicant provides two working examples of the invention.

Fourth, the nature of the invention is not complex and not considered a new or emerging technology. The *M.P.E.P.* § 2164.03 states that the level of knowledge in an art indicates the level of predictability. In *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362 (Fed. Cir. 1999), the Court states that consideration of an invention in a new technology impacts on how the *Wands* factors are evaluated. The Court also states that the unpredictable arts include areas of technology and research that require further development and understanding. *Id.* at 1372. Applicant submits that the technology of crossing *impatiens* is not a new or emerging technology and that the technology is not complex such that undue experimentation is likely required to carry out Applicant's invention.

Fifth, the state of the prior art is mature as discussed above under factor four. The result is that with the amount of information provided in the specification, one of ordinary skill in the art would be able to make and/or use the invention.

Sixth, there is predictability in crossing impatiens plants to a certain degree although Applicant's invention is novel and non-obvious. As noted above, the crossing of impatiens plants have been successful as stated above for other characteristics such as color of the flowers. Although no crossings have been attempted or none that have produced impatiens having a trailing habit as claimed, there is no reason for one of ordinary skill in the art to question the method as disclosed in the instant specification. The two working examples provided in the specification clearly describe the characteristic of the trailing habit produced in the plants. Dr. Trees declaration further provides evidence of the working examples.

Finally, the breadth of the claims is not overly broad. As noted below, Applicant has amended claim 31 to include the additional steps of planting the resultant impatiens seed and growing into plants and selecting an interspecific impatiens plant having a trailing habit.

Applicant submits that for these reasons, the claimed invention does not require undue experimentation.

However, in order to expedite prosecution of the instant application, Applicant has amended claim 31 to include the additional steps of planting the resultant impatiens seed and growing into plants and selecting an interspecific impatiens plant having a trailing habit. Additionally, Applicant notes the following. On page 4 of the Office Action dated January 28, 2003, the Examiner states that the previous claims encompass impatiens having one fixed characteristic, low or procumbent habit but an enormous number of other undisclosed phenotypic traits are not disclosed. On page 4 of the Office Action dated August 26, 2003, the Examiner states that Applicant has not disclosed in the specification all the phenotypic characteristics from the claimed progenies. Applicant submits that the other phenotypic traits that are not disclosed and are not claimed are not inconsequential. The independent claim now specifically requires the characteristic of a trailing habit. Not only is it not required to disclose all phenotypic characteristics, but it is impossible to disclose all phenotypic characteristics. Nevertheless, Applicant discloses quite a number of

characteristics for each example, such as those on pages 7-9 for example 1. Additionally, the examples provided in the instant specification describe the trailing habit in detail. As indicated below, Applicant is only required to provide one working example. However, Applicant has provided two working examples in the specification.

The inquiry into whether the description requirement is met is determined on a case-by-case basis and is a question of fact. Section 2163 *Manual of Patent Examining Procedure* (8<sup>th</sup> Edition, Rev. 1, Feb. 2003). When a question regarding the adequacy of the written description arises, the fundamental factual inquiry is whether the specification conveys to those skilled in the art, as of the filing date sought, that applicant was in possession of the invention being claimed. Section 2163.02 *Manual of Patent Examining Procedure* (8<sup>th</sup> Edition, Rev. 1, Feb. 2003). Possession can be shown in a number of ways. For example, an Applicant can show possession by: (1) an actual reduction to practice of the claimed invention; (2) a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention; or (3) any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Id.*

A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the Examiner to rebut the presumption. Section 2163.04 *Manual of Patent Examining Procedure* (8<sup>th</sup> Edition, Rev. 1, Feb. 2003). The Examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. *Id.* The Examiner has the initial burden of presenting by a preponderance of the evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention as defined by the claims. *Id.* "A general allegation of unpredictability in the art is not a sufficient reason to support a rejection for lack of adequate written description." *Id.* The *Manual of Patent Examining Procedure* even cautions Examiners that "rejection of an original claim

for lack of written description should be rare." (See Section 2163 *Manual of Patent Examining Procedure* (8<sup>th</sup> Edition, Rev. 1, Feb. 2003)).

The U.S. PTO has issued Guidelines governing its internal practice for assessing whether the specification contains an adequate written description of the invention being claimed. In its Guidelines, the PTO has determined that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics..., i.e., the complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, January, 2001 *Guidelines*, 66 Fed. Reg. at 1106.

Contrary to the arguments made by the Examiner, Applicant submits that the specification adequately describes the method of producing an interspecific impatiens plant encompassed within the scope of the invention being claimed. First, as specifically recommended by the *Guidelines*, Applicant has provided an actual reduction to practice of the claimed invention by way of the working examples. Second, Applicant has provided a description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. This is seen from the numerous characteristics of the plant as claimed, such as those described on pages 6-9 for example 1.

Accordingly, Applicant respectfully request withdrawal of the rejection of claims 31 and 34 under 35 U.S.C. § 112, first paragraph, for not enabling any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope of the claims.

## CONCLUSION

Applicants respectfully submit that the claims comply with the requirements of 35 U.S.C. Section 112. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

Should the Examiner have any questions concerning the above, she is respectfully requested to contact the undersigned at the telephone number listed below. If the Examiner notes any further matters which the Examiner believes may be expedited by a telephone interview, the Examiner is requested to contact the undersigned.

If any additional fees are incurred as a result of the filing of this paper, authorization is given to charge deposit account no. 23-0785.

Respectfully submitted,

Mario Guillen

A handwritten signature in black ink, appearing to read "Lisa V. Mueller", written over a horizontal line.

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